KONICA MINOLTA

**Section 5: 510(k) Summary**

**Submitter:** Konica Minolta Medical and Graphic

Shigeyuki Kojima
Manager
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan

**Contact Person:** Jillian M. Reed
Regulatory and Clinical Affairs Consultant
Reed Technical Associates, LLC
25 Walnut Street
Monroe, CT 06468
O: (203) 459-0659
F: (203) 538-3960
jillianreed@charter.net

**Date Prepared:** March 11, 2011

**Classification Name:** Full Field Digital Mammography System

**Common Name:** Xpress Digital Mammography System

**Proprietary Name:** Xpress Digital Mammography System

**Predicate Devices:** P050014
Fuji Computed Radiography Mammography Suite (FCRMS).

**Device Description:**

Konica Minolta's Xpress Digital Mammography is a software device that is used in conjunction with currently marketed Konica Minolta computed radiography systems to acquire Full Field Digital Mammography Images. Digital mammography can be performed with the specified Konica Minolta computed radiography systems including the activated Xpress Digital Mammography software using any mammography x-ray unit legally marketed in the U.S.. Konica Minolta does not specify a mammography x-ray unit for use with the specified Konica Minolta computed radiography system with the activated Xpress Digital Mammography software.

The components of the specified Konica Minolta computed radiography systems for digital mammography include either REGIUS Models 190 (K052095) or 210 (K092717) Direct Digitizers and the REGIUS Console CS-3000 medical image processing workstation (K051523) with optional bar code reader accessories.

The x-ray images produced by the legally marketed x-ray unit are captured on a REGIUS image plate and digitized using either REGIUS Model 190 or 210 Direct Digitizers. The digitized images are imported into the REGIUS Console CS-3000 workstation. The REGIUS Console CS-3000 is identical to the REGIUS Console CS-3000 described in K051523 with the Xpress Digital Mammography software activated. The Xpress Digital Mammography software provides a high resolution reading capability and display options specific to the review of mammographic image.

Soft copy images can be transferred to any legally marketed diagnostic viewing station that accepts DICOM 3 input. Hard copy images can be generated using any printer legally marketed for use in digital mammography that supports DICOM basic grayscale print management service with a maximum 50 micrometer pixel pitch and film minimum optical density of at least 3.6.

**Intended Use:**

The Konica Minolta Xpress Digital Mammography System is a software device that is used in conjunction with a specified Konica Minolta computed radiography system to produce full field digital mammography images. The Xpress Digital Mammography software with a specified Konica Minolta computed radiography system is designed to replace screen-film based systems for the production of mammographic images. The device is intended to be used for screening and diagnosis of breast cancer.

**Substantial Equivalence:**

Results from the Non-Clinical and Clinical testing performed has shown that the Konica Minolta Xpress Digital Mammography System Software is substantially equivalent to the Fuji Computed Radiography Mammography Suite (FCRMS), #P050014 for its intended use.

**Discussion of Non-Clinical Testing Performed:**

In accordance with the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Full Field Digital Mammography" dated November 5, 2010, Konica Minolta conducted the following physical performance tests required to demonstrate the substantial equivalence of the Xpress Digital Mammography System software used in conjunction with the Xpress CR imaging system:

**Sensitometric Response**

Testing was conducted to evaluate the sensitometric response of the REGIUS image plate and exposed by the Senographe DMR x-ray unit.

A REGIUS image plate was inserted into the holder and exposed under IEC62220-1-2 RQA-M2 conditions (28kV, Mo target and Mo filter, 2 mm Aluminum filter).

The incident dose to the REGIUS image plate was measured using each of the plates and compared with the dose with no plate in the beam. Each exposed image plate was read

with the REGIUS Model 190 Digitizer and the raw data was evaluated to determine the average pixel value for the image area as a measure of the sensitometric response.

The relationship between the pixel value and radiation exposure is shown in Figure 5-1. The data shows that the linear relationship between pixel value and exposure was maintained for all exposure conditions.

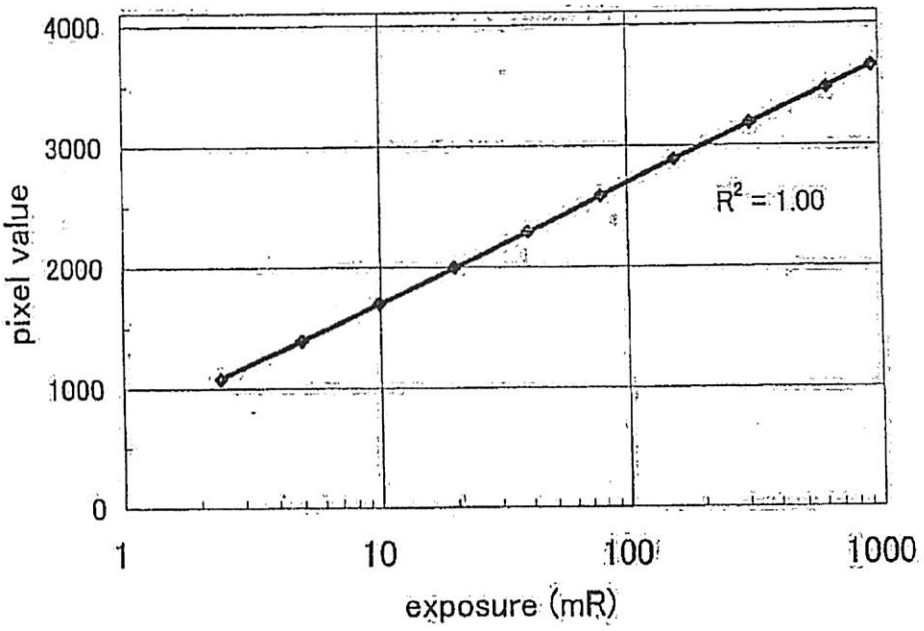


**Figure 5-1: Sensitometric Response**

**Spatial Resolution**

The modulation transfer function (MTF) of Xpress Digital Mammography was calculated to evaluate the spatial resolution properties of the image acquisition system. Testing was conducted under IEC62220-1-2 RQA-M2 conditions.

The presampling MTF was measured using the edge technique. An edge device made of tungsten (0.5 mm thickness) was placed on top of the x-ray unit breast support table. Separate exposures were performed with the edge slightly tilted to the scan or sub-scan direction. A CP1M200 REGIUS image plate was inserted into the holder and exposed under RQA-M2 conditions for each scan direction.

Each exposed REGIUS image plate was read with the REGIUS Model 190 Digitizer at 43.75 µm and the presampling MTF was measured from the image of the edge device in accordance with IEC62220-1-2. The presampling MTF is provided in Figure 5-2.

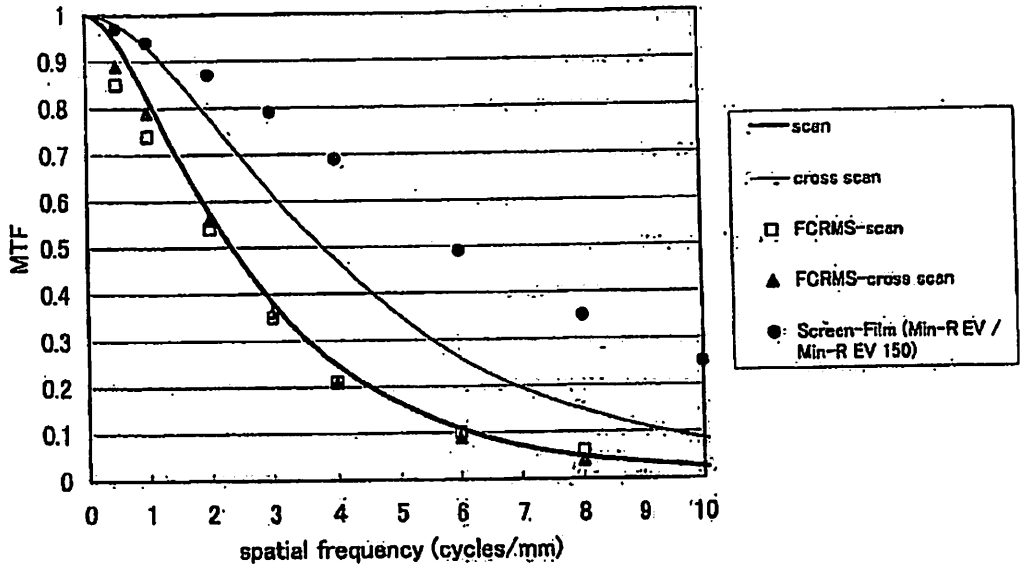


**Figure 5-2: Spatial resolution – Presampling MTF**

Data extracted from the published Summary of Safety and Effectiveness Data for the MTF of unprocessed images generated using the Fuji Computed Radiography Mammography Suite (FCRMS) Fujifilm Medical System U.S.A., Inc.(P050014)[1] is included in Figure 5-2 for a comparison. The data provided in Figure 5-2 demonstrates that the spatial resolution of the proposed Konica Minolta's Xpress Digital Mammography is equivalent or better than that of the Fuji Computed Radiography Mammography Suite (FCRMS) Fujifilm Medical System U.S.A., Inc. (P050014).

**Noise Analysis**

Noise power spectrum (NPS) for the image acquisition system that constitutes the Xpress Digital Mammography was determined as a measure of noise analysis, at several different radiation exposures. Testing was conducted under IEC62220-1-2 RQA-M2 conditions.

Plots of the NPS as a function of spatial frequency (cycle/mm) in the scan and cross scan directions are provided in Figure 5-3 and 5-4.

[1] http://www.fda.gov/cdrh/pdf5/p050014b.pdf

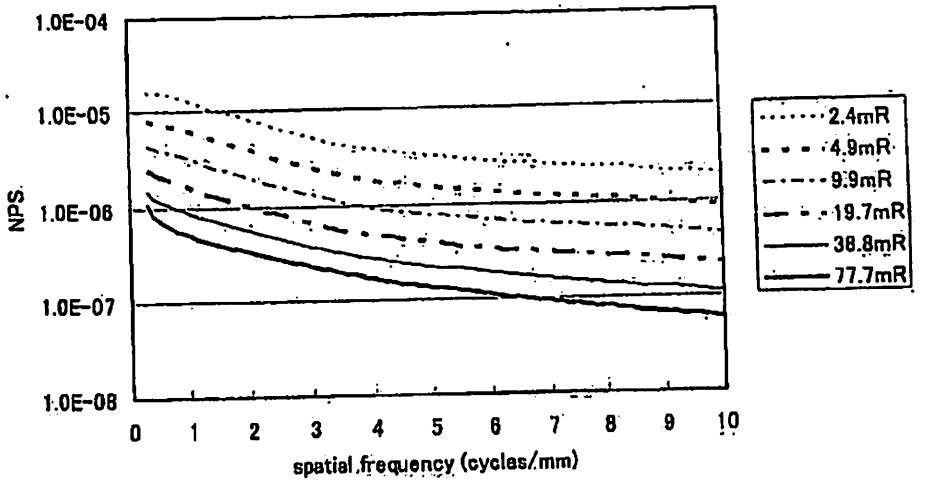


**Figure 5-3: Noise Analysis – NPS as a function of spatial frequency (cycle/mm) in the scan direction**

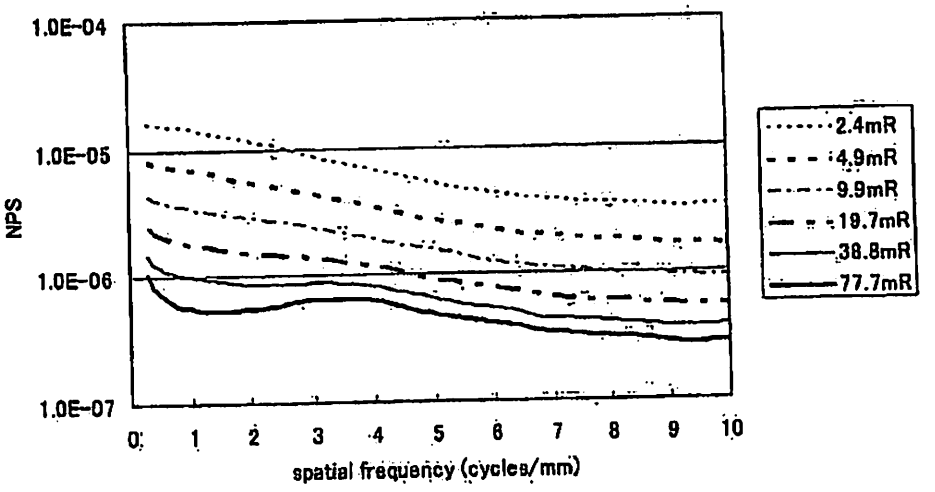


**Figure 5-4: Noise Analysis – NPS as a function of spatial frequency (cycle/mm) in the cross scan direction**

**Signal-to-Noise Ratio Transfer - DQE**

DQE for the image acquisition system was measured at several different radiation exposures and expressed as a function of spatial frequency as shown in Figures 5-5 and 5-6. Testing was conducted under IEC62220-1-2 RQA-M2 conditions.

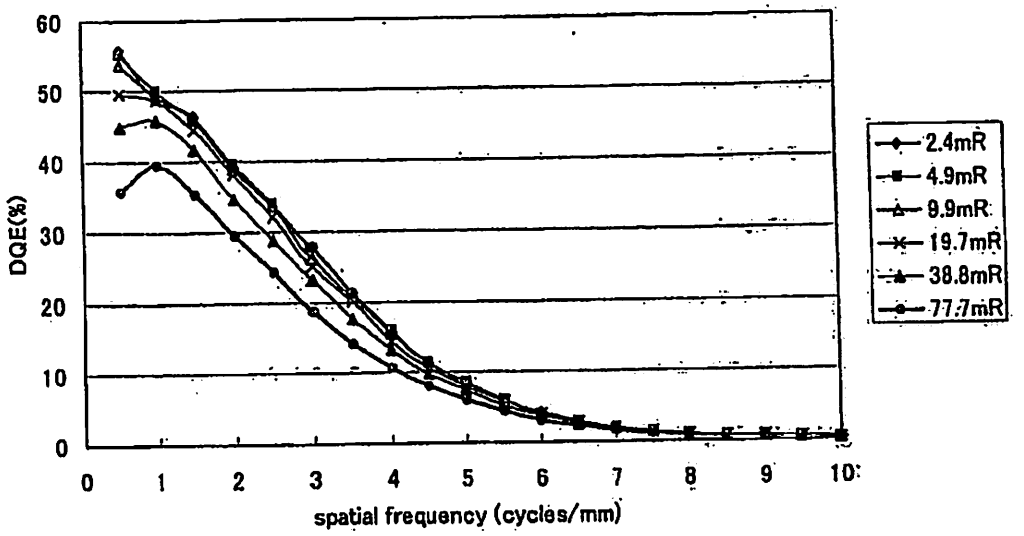


**Figure 5-5: Signal-to-Noise Ratio Transfer – DQE as a function of spatial frequency (cycle/mm) in the scan direction**

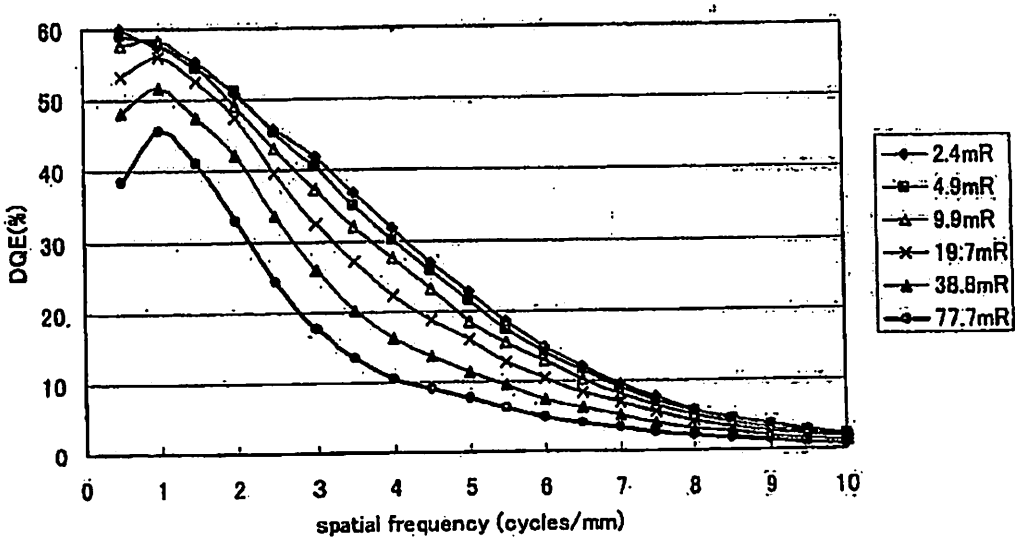


**Figure 5-6: Signal-to-Noise Ratio Transfer – DQE as a function of spatial frequency (cycle/mm) in the cross scan direction**

### Dynamic Range

The dynamic range is indicated by using DQE as a function of radiation exposure level as shown in Figures 5-7, 5-8 and 5-9.

The data provided in Figure 5-9 demonstrates that the average DQE of the proposed Konica Minolta's Xpress Digital Mammography is equivalent or better than that of the Fuji Computed Radiography Mammography Suite (FCRMS) Fujifilm Medical System U.S.A., Inc. (P050014).

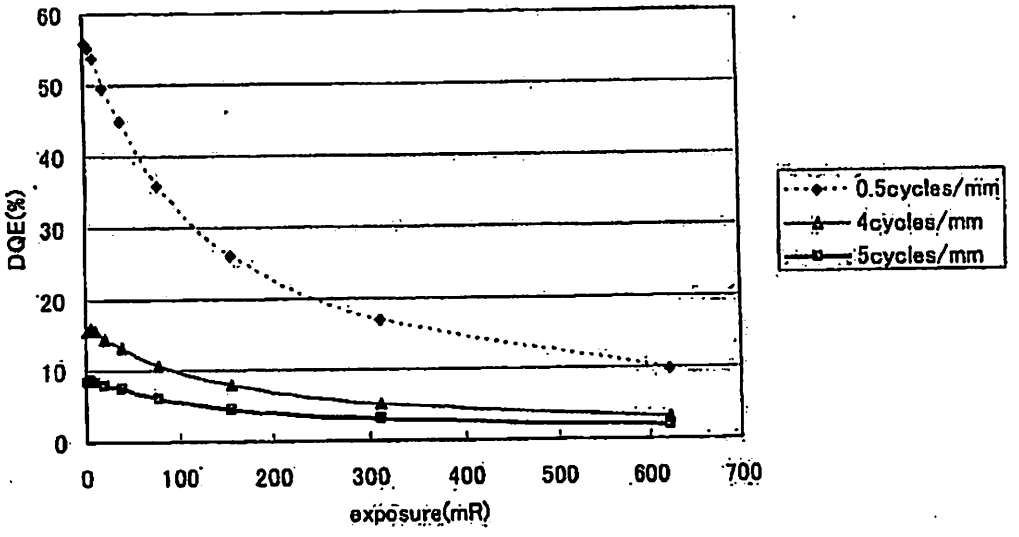


**Figure 5-7: Dynamic Range – DQE as a function of radiation exposure level in the scan direction**

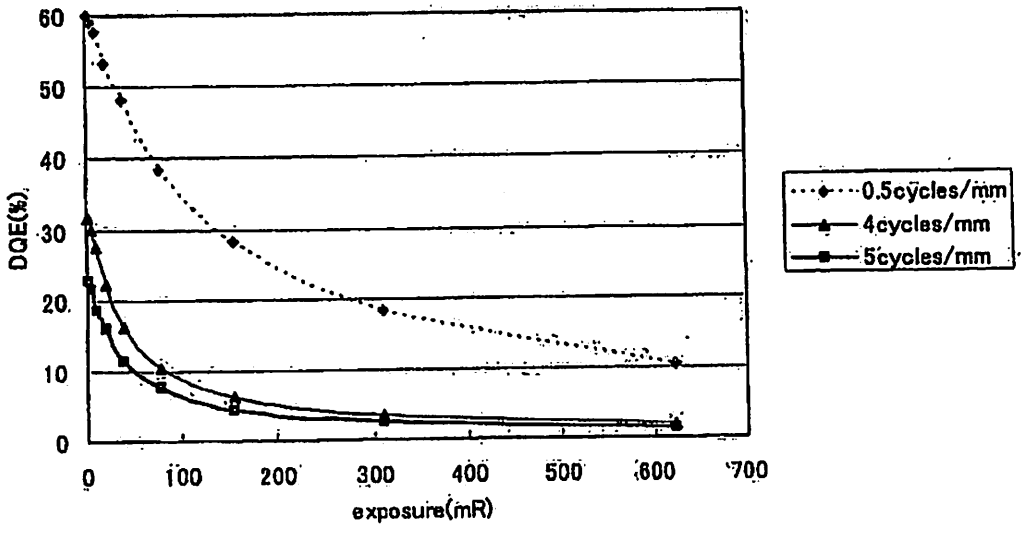


**Figure 5-8: Dynamic Range – DQE as a function of radiation exposure level in the cross scan direction**

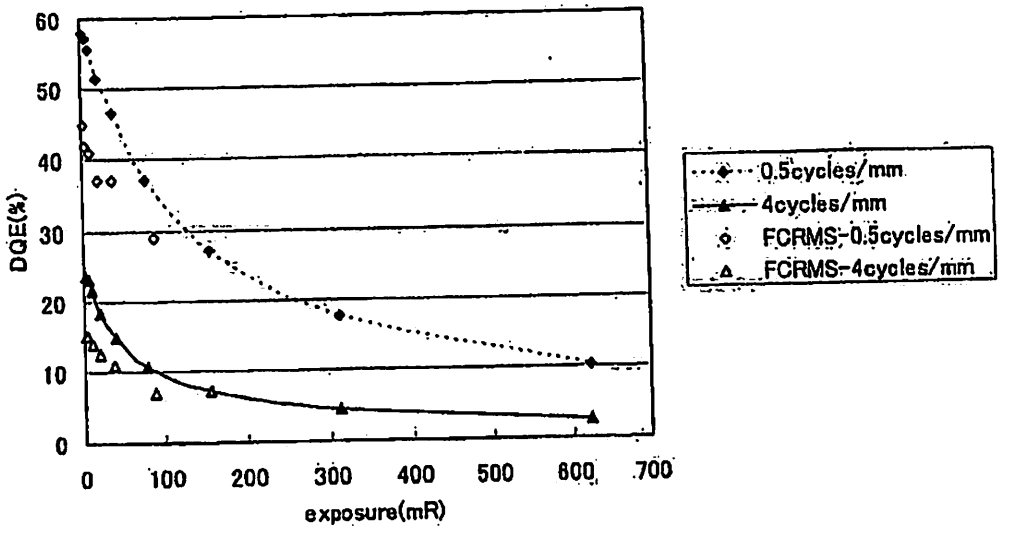


**Figure 5-9: Dynamic Range – Average DQE as a function of radiation exposure level in comparison with a predicate device**

**Image Erasure and Fading**

a. Image Erasure

Image erasure was assessed by reading an image after erasing. The previous image was exposed under 28kV, Mo target and Mo filter, 32mAs, 2 mm Aluminum filter conditions. No residual signals were observed.

b. Fading

The results of the image fading test at three different temperatures are provided in Figure 5-10. The initial decline in luminescence intensity during 2 hours following the exposure was 20 % at 30 degrees Celsius.

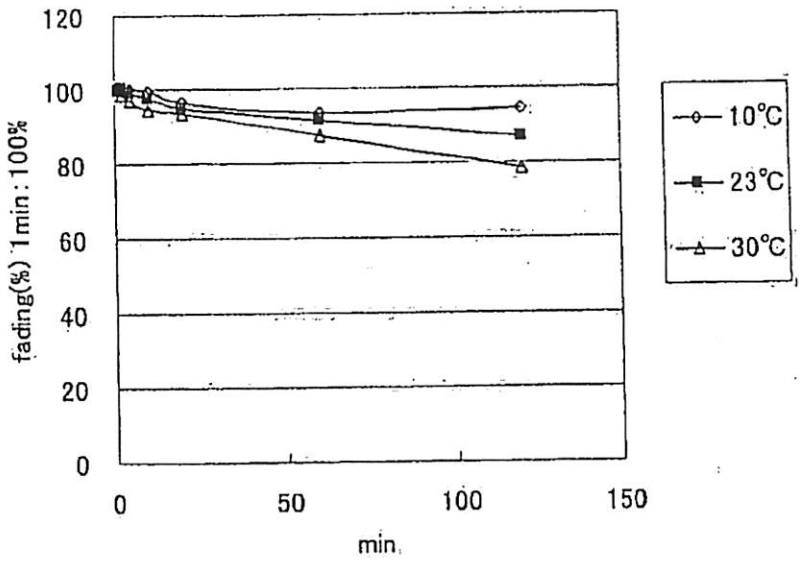


**Figure 5-10: Fading**

c. Image Retention

Image retention was assessed by repeating exposures and erasures at 100 times. The previous image was exposed under 28kV, Mo target and Mo filter, 32mAs, 2 mm Aluminum filter conditions. No signal was observed.

d. Fogging after Exposure to Room Light

No signal fogging or depletion was observed after 5 minutes exposure to light of 7000 lx luminance. The luminance is more than ten times greater than that of an ordinary room condition.

**Repeated Exposure Test**

After 100 cycles of exposures and erasures, the Lag value was calculated in accordance with IEC62220-1-2, Annex A.2.

The resultant lag value was 0.0047.

**Phantom Testing**

The performance of the Xpress Digital Mammography image acquisition system was assessed using the contrast-detail mammography (CDMAM) phantom V3.4 and the Mammographic Accreditation (ACR) phantom NA18-220. The phantom images were generated by using the CDMAM and ACR phantoms at standard clinical conditions (28kV, Mo target and Mo filter). In each condition three images were acquired.

The phantom images were printed on dry films by using DRYPRO Model 793, #K042133, for a hard-copy display testing, and the films were observed on a lightbox. The lightbox luminance was greater than 7,000 cd/m$^2$ and the ambient illuminance was less than 10 lx. A Cedara I-ReadMammo (Merge Healthcare, K040468) was used for a soft-copy display testing. The monitor luminance was greater than 400 cd/m$^2$ and the ambient illuminance was less than 10 lx.

Three observers participated in the rating both the CDMAM phantom and the ACR phantom. Each observer rated all the images taken. Observer experience is listed in Table 5-1.

**Table 5-1: Observer Experience**

| Observer | Experience |
|---|---|
| A | Seven years' experience of the phantom scoring |
| B | Five years' experience of the phantom scoring |
| C | Five years' experience of the phantom scoring |

The average scores of all three observers were calculated to create the contrast-detail (C-D) diagrams. The C-D diagrams generated from the CDMAM phantom images are provided in Figure 5-11, 5-12 and 5-13.

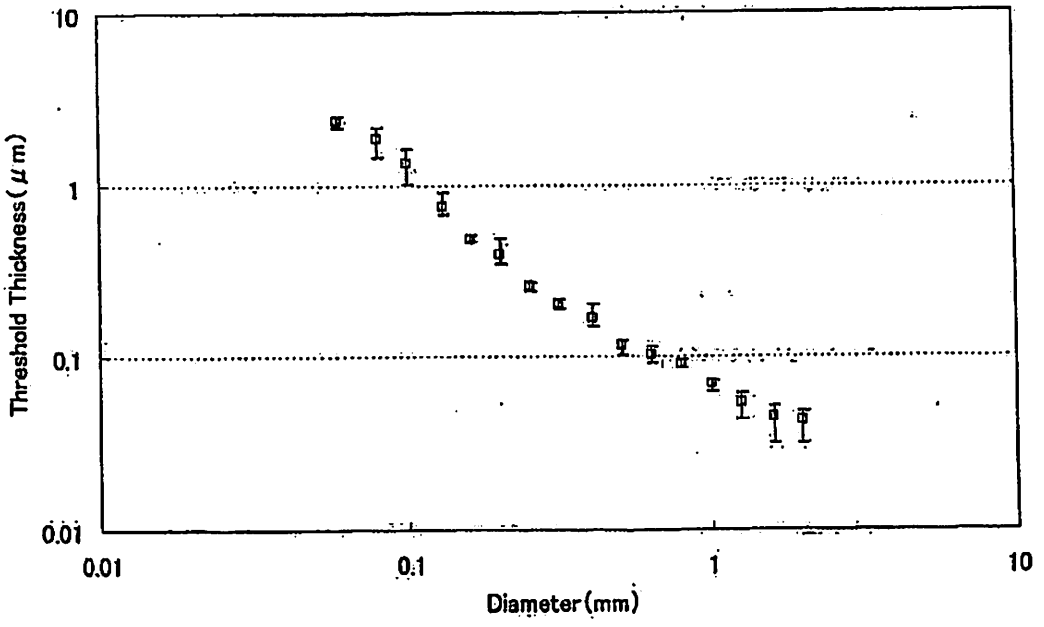


**Figure 5-11: C-D diagram (hard-copy display, 2.94mGy)**

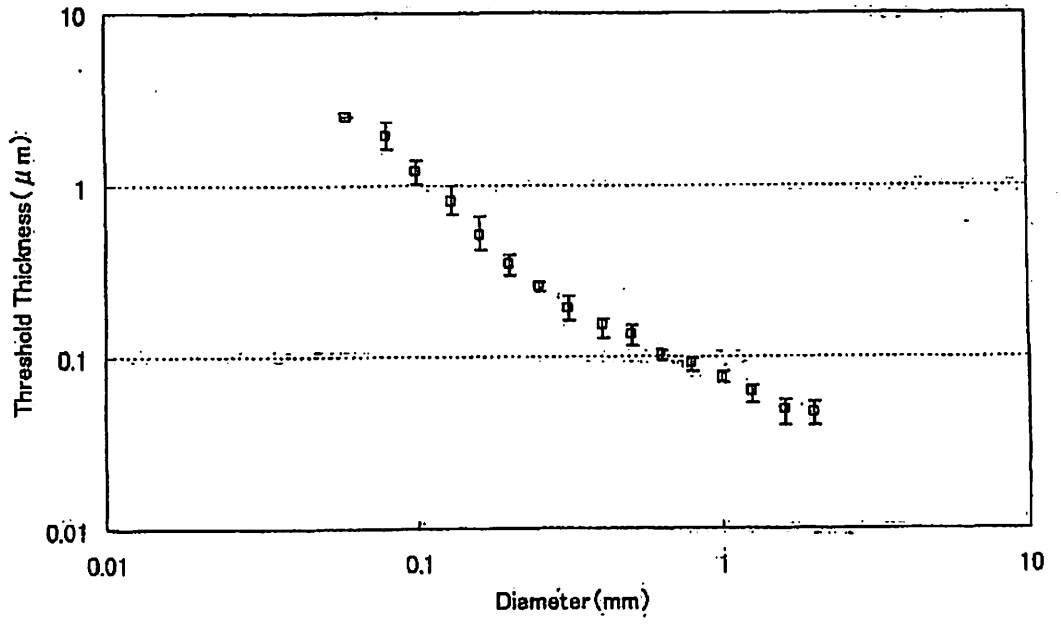


**Figure 5-12: C-D diagram (soft-copy display, 2.94mGy)**

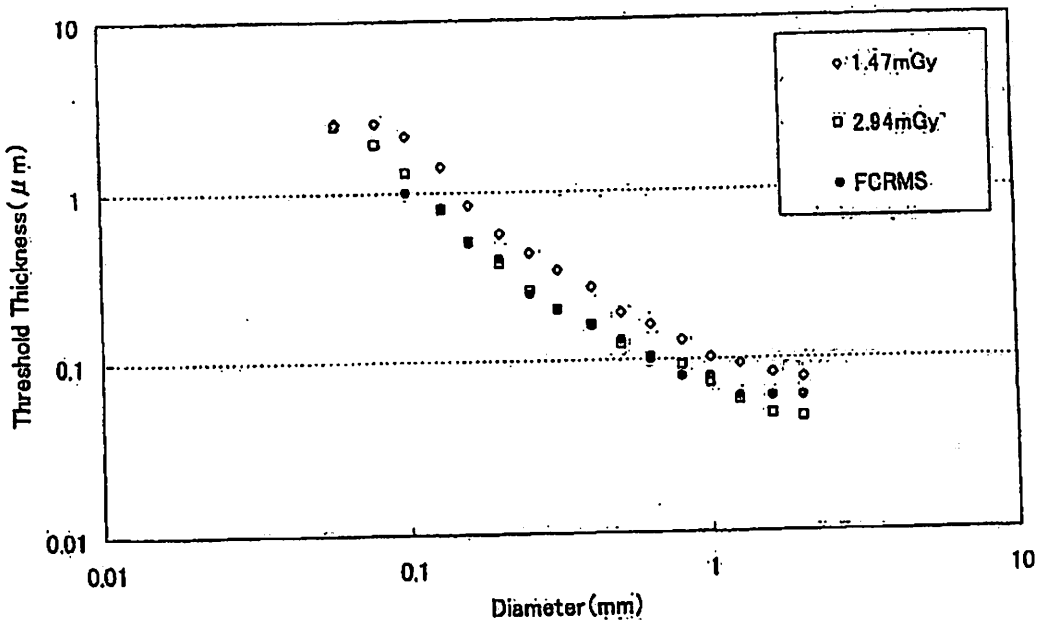


**Figure 5-13: C-D diagram (average)**

The image quality factor (IQF) is the sum of the products of the diameters of each of the smallest scored objects and their relative contrast. The IQF were calculated at a diameter no larger than 1.8mm and a thickness no larger than 2.5um and provided in Figure 5-14.

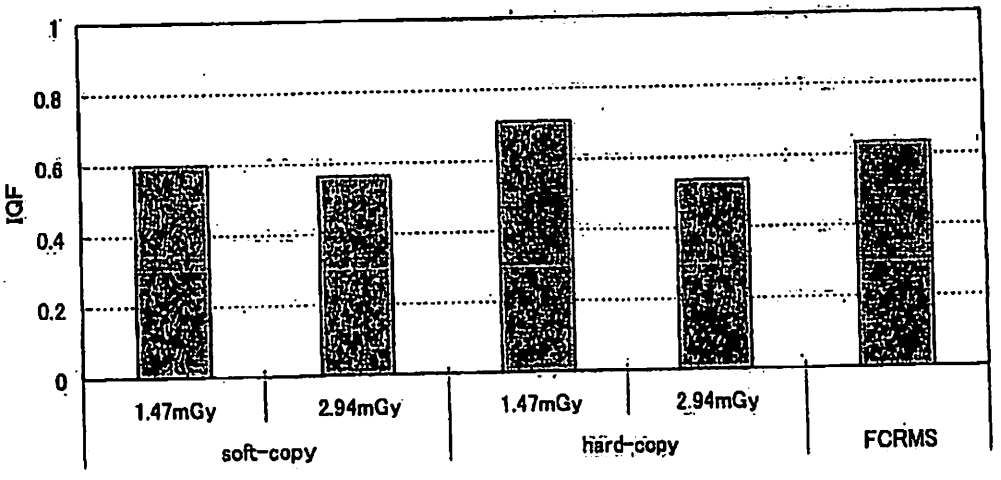


**Figure 5-14: IQF results**

The average ACR phantom scores for fibers, specks, and masses are provided in Tables 5-2, 5-3, 5-4 and 5-5.

**Table 5-2: ACR phantom scores with hard-copy display**

| Scoring Criteria | ACR Phantom* |
|---|---|
| Fibers | 5.7 |
| Specks | 4.0 |
| Masses | 4.4 |

*Each value represents the average scores from 3 experienced readers

**Table 5-3: ACR phantom scores with soft-copy display**

| Scoring Criteria | ACR Phantom* |
|---|---|
| Fibers | 5.4 |
| Specks | 4.1 |
| Masses | 4.8 |

*Each value represents the average scores from 3 experienced readers

**Table 5-4: ACR Phantom Scores of predicated device**

| Scoring Criteria | ACR Phantom* |
|---|---|
| Fibers | 5.0 |
| Specks | 3.8 |
| Masses | 3.6 |

* The predicated device is Fuji Computed Radiography Mammography Suite (FCRMS) Fujifilm Medical System U.S.A., Inc. (P050014)

**Table 5-5: ACR Phantom Scores of a film-screen system**

| Scoring Criteria | ACR Phantom* |
|---|---|
| Fibers | 4.9 |
| Specks | 3.8 |
| Masses | 4.0 |

* The film-screen system is Min-R EV/Min-R EV150. Each value represents the average scores from 3 experienced readers.

The data provided in Tables 5-2, 5-3, 5-4 and 5-5 demonstrates that the scores of ACR Phantom of the proposed Konica Minolta's Xpress Digital Mammography is equivalent or better than those of the Fuji Computed Radiography Mammography Suite (FCRMS) Fujifilm Medical System U.S.A., Inc. (P050014) and the film-screen system (Min-R EV/Min-R EV 150).

**Discussion of Clinical Testing Performed:**

**Objectives:**

The purpose of the clinical study was to evaluate the safety and effectiveness of the Konica Minolta Medical Imaging Xpress Digital Mammography System (Xpress Digital) for screening and diagnosis of breast cancer. The trial design, as defined in this section, sought to compare the combined area under the curve (AUC), as well as sensitivity, specificity and features analyses of Xpress Digital to conventional screen-film mammography methods in detecting breast cancer.

**Methods:**

Konica Minolta conducted a prospective, non-randomized, non-blinded clinical trial to acquire both standard screen-film mammograms and Xpress Digital mammograms at 11 clinical investigational centers. The final study cohort consisted of 210 subjects: 60 pathology proven cancers, 130 benign abnormal subjects (benign biopsy findings), and 20 negative subjects (confirmed by negative one year follow-up mammography). Both the screen-films images and the Xpress Digital images were acquired, randomized and evaluated.

Eleven radiologists who were blinded to the details of the subject histories, mammography films or results interpreted all 210 screen-film and Xpress Digital images. The radiologists scored each case with a BIRADS score of 0, 1, 2, 3, 4, or 5 and assigned a probability of malignancy to each case on a continuous scale from 0 – 100%.

ROC curves were generated from the Xpress Digital and screen-film results and the areas under the curve were compared. Cases assigned a BIRADS score of 0: requiring further evaluation (i.e., magnification or spot mammography, ultrasound, MRI, biopsy, etc.) were classified as recalls. The sensitivity of each mammography modality was obtained by determining the radio of the number of correct positive readings to (assignment of a BIRADS score of 4 or 5) to the total number of true positive cases. Specificity was obtained by determining the ratio of the number of true negative readings to the total number of the true negative cases (BIRADS score 1, 2, or 3).

Features analyses were then performed were half the readers comparing side-by-side comparisons of screen-film and Xpress Digital images of 100 cases (60 pathology proven cancers and 40 abnormal benign biopsy cases) and the other half comparing soft copy Xpress Digital images to hard-copy printed Xpress Digital images of 60 pathology proven cancers. In addition to the conspicuity of the pathology, several other characteristics of the images and anatomic features were compared.

**Results:**

The analysis of the AUC from the ROC curves indicated that the Xpress Digital Mammography System is non-inferior to Screen-Film Mammography. The observed difference in the areas was about 1% and the upper one-sided 95% confidence limits were less than 5%.

The specificity for the Xpress System was non-inferior to the specificity of Screen-Film mammography. The difference in specificities was about 2% favoring the Xpress system and the upper one-sided confidence limit using GEE analysis which accounts for the subject image and reader correlations was less than 0.05. A supportive analysis of specificity using the ROC curve at a sensitivity of 46% also demonstrated the non-inferiority with an upper one-sided confidence limit less than 0.05.

The sensitivity for the Xpress system was not non-inferior by GEE analysis, but an analysis using the ROC curve indicated that at a specificity of 90%, the upper one-sided confidence limit on the sensitivity of the Screen-Film minus the Xpress system was less than 0.10. The finding that the sensitivity of a Xpress system compared to Screen-Film is not surprising considering that the vast majority of subjects recruited into the trial were recommended for biopsy based on a suspicious Screen-Film examination. Unfortunately there were too few subjects in the screening sample in this trial to allow an adjustment method to be done for the associated bias.

The features analysis showed that the Xpress system was favored for visualization of the skin line, but all other features there was little evidence of a difference between the two systems. This indicates that the Xpress system does not lose detail that can be seen on Screen-Film images. Likewise, there did not appear to be a trend favoring hard image to soft image for the Xpress system.

These results indicate that the Xpress Digital Mammography System provides images that are useful in the detection of cancer which are not inferior to those of conventional Screen-Film images.

**Conclusion:**

The Xpress Digital Mammography System is safe and effective for screening and diagnosis of breast cancer based on ROC analyses, sensitivity, specificity, recall rates, and features analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Konica Minolta Medical and Graphic
% Ms. Jillian M. Reed
Regulatory and Clinical Affairs Consultant
Reed Technical Associates, LLC
25 Walnut Street
MONROE CT 06468

JAN 19 2012

Re: K110717
Trade/Device Name: Konica Minolta Xpress Digital Mammography System
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: December 20th, 2011
Received: December 21st, 2011

Dear Ms. Reed:

This letter corrects our substantially equivalent letter of December 23rd, 2011.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

# Indications for Use

510(k) Number (if known) : K110717

Device Name : Konica Minolta Xpress Digital Mammography System

Indications for Use:

The Konica Minolta Xpress Digital Mammography System is a software device that is used in conjunction with a specified Konica Minolta computed radiography system, REGIUS Model 190 or REGIUS Model 210 with REGIUS Cassette Plate CP1M200 and the REGIUS Console CS-3000, and a mammography x-ray unit, to produce full field digital mammography images. The Xpress Digital Mammography software with a specified Konica Minolta computed radiography system is designed to replace screen-film based systems for the production of mammographic images. The device is intended to be used for screening and diagnosis of breast cancer. The mammographic images can be interpreted by a qualified physician using either hard copy film or soft copy display at a workstation.

Prescription Use ___×___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110717